HFI-35

4/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

d1805b

Refer to: CFN 1123483

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

May 1, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Billy C. Moore, President
Virginia Home Medical Services, Inc.
206 E. Washington Street
Bedford, Virginia 24523

Dear Mr. Moore:

The Food and Drug Administration (FDA) conducted an inspection of your Oxygen U.S.P. manufacturing facility in Bedford, Virginia on April 13, 1998. During the inspection, the following deviations from Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed, which cause your Oxygen U.S.P. to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act):

1. Failure to conduct an odor test on each high-pressure cylinder filled with Oxygen U.S.P. at the time of testing to assure that it is in conformance with appropriate specifications for identity, strength, quality, and purity prior to release.

2. Failure to adequately calibrate and to document the calibration of the oxygen analyzer used during the testing of Oxygen U.S.P. Your facility uses room air to calibrate the oxygen analyzer rather than nitrogen to perform the low end calibration.

3. Failure to perform or have appropriate documentation to demonstrate that adequate pre-fill, fill, and post-fill operations were performed on each high-pressure cylinder, including an odor test, prior to release.

4. Failure to establish written procedures and provide documentation to assure that each person engaged in the transfilling of Oxygen U.S.P. has the education, training, or experience to enable them to perform their assigned functions.

5. Failure to establish a written procedure for the calibration of equipment used to test and release Oxygen U.S.P.

At the conclusion of the inspection, Mr. Joel K. Godfrey, General Manager, was given a written list of inspectional observations (FDA-483, enclosed) which was discussed with him.

The aforementioned violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a compressed medical gases guideline which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,

William M. Ment

William M. Ment
Acting Director, Baltimore District

Enclosures